

## 14.28 Nebulizers

### ***HCPCS CODES***

The appearance of a code in this section does not necessarily indicate coverage

#### *Equipment:*

E0565	Compressor, air power source, for equipment which is not self-contained or cylinder driven
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic
E0585	Nebulizer, with compressor and heater
K0269	Aerosol compressor, adjustable pressure, light duty for intermittent use
K0270	Ultrasonic generator with small volume ultrasonic nebulizer
K0501	Aerosol compressor, battery powered, for use with small volume nebulizer

#### *Accessories:*

A4619	Face tent
A4621	Tracheostomy mask or collar
A7003	Administration set, small volume nonfiltered pneumatic nebulizer, disposable
A7004	Small volume nonfiltered pneumatic nebulizer, disposable
A7005	Administration set, small volume nonfiltered pneumatic nebulizer, non-disposable
A7006	Administration set, small volume filtered pneumatic nebulizer
A7007	Large volume nebulizer, disposable, unfilled, used with aerosol compressor
A7008	Large volume nebulizer, disposable, prefilled, used with aerosol compressor
A7009	Reservoir bottle, non-disposable, used with large volume ultrasonic nebulizer
A7010	Corrugated tubing, disposable, used with large volume nebulizer, 100 feet

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A7011	Corrugated tubing, non-disposable, used with large volume nebulizer, 10 feet
A7012	Water collection device, used with large volume nebulizer
A7013	Filter, disposable, used with aerosol compressor
A7014	Filter, non-disposable, used with aerosol compressor or ultrasonic generator
A7015	Aerosol mask, used with DME nebulizer
A7016	Dome and mouthpiece, used with small volume ultrasonic nebulizer
A7017	Nebulizer, durable, glass or autoclavable plastic, bottle type, not used with oxygen
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1372	Immersion external heater for nebulizer

**Inhalation Drugs:**

E0590	Dispensing fee for covered drug administered through DME nebulizer
J2545	Pentamidine isethionate, inhalation solution, per 300 mg, administered through DME
J7051	Sterile saline or water, up to 5 cc
J7608	Acetylcysteine, inhalation solution administered through DME, unit dose form, per gram
J7618	Albuterol, inhalation solution administered through DME, concentrated form, per milligram
J7619	Albuterol, inhalation solution administered through DME, unit dose form, per milligram
J7628	Bitolterol mesylate, inhalation solution administered through DME, concentrated form, per milligram
J7629	Bitolterol mesylate, inhalation solution administered through DME, unit dose form, per milligram
J7631	Cromolyn sodium, inhalation solution administered through DME, unit dose form, per 10 milligrams
J7635	Atropine, inhalation solution administered through DME, concentrated form, per milligram
J7636	Atropine, inhalation solution administered through DME, unit dose form, per milligram

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J7637	Dexamethasone, inhalation solution administered through DME, concentrated form, per milligram
J7638	Dexamethasone, inhalation solution administered through DME, unit dose form, per milligram
J7639	Dornase alpha, inhalation solution administered through DME, unit dose form, per milligram
J7642	Glycopyrrolate, inhalation solution administered through DME, concentrated form, per milligram
J7643	Glycopyrrolate, inhalation solution administered through DME, unit dose form, per milligram
J7644	Ipratropium bromide, inhalation solution administered through DME, unit dose form, per milligram
J7648	Isoetharine HCL, inhalation solution administered through DME, concentrated form, per milligram
J7649	Isoetharine HCL, inhalation solution administered through DME, unit dose form, per milligram
J7658	Isoproterenol HCL, inhalation solution administered through DME, concentrated form, per milligram
J7659	Isoproterenol HCL, inhalation solution administered through DME, unit dose form, per milligram
J7668	Metaproterenol sulfate, inhalation solution administered through DME, concentrated form, per 10 milligrams
J7669	Metaproterenol sulfate, inhalation solution administered through DME, unit dose form, per 10 milligrams
J7680	Terbutaline sulfate, inhalation solution administered through DME, concentrated form, per milligram
J7681	Terbutaline sulfate, inhalation solution administered through DME, unit dose form, per milligram
J7682	Tobramycin, unit dose form, 300 mg, inhalation solution (administered through DME)
J7683	Triamcinolone, inhalation solution administered through DME, concentrated form, per milligram
J7684	Triamcinolone, inhalation solution administered through DME, unit dose form, per milligram
J7699	NOC drugs, inhalation solution administered through DME
K0182	Water, distilled, used with large volume nebulizer, 1000 ml
K0283	Saline solution, per 10 ml, metered dose dispenser, for use with inhalation drugs

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K0529 Sterile water or sterile saline, 1000 ml, used with large volume nebulizer

### **HCPCS Modifiers**

**KO** Single drug unit dose formulation

**KP** First drug of a multiple drug unit dose formulation

**KQ** Second or subsequent drug of a multiple drug unit dose formulation

### **Benefit Category**

Durable Medical Equipment

### **Reference**

Coverage Issue Manual 60-9

### **Definitions**

#### *Equipment:*

In this policy, the actual equipment (i.e., electrical device) will generally be referred to as either a compressor (when nebulization of liquid is achieved by means of air flow) or as a generator (when nebulization of liquid is achieved by means of ultrasonic vibrations). The term nebulizer is generally used for the actual chamber in which the nebulization of liquid occurs and is an accessory to the equipment. The nebulizer is attached to an aerosol compressor or an ultrasonic generator in order to achieve a functioning delivery system for aerosol therapy.

Code E0565 describes an aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m and is capable of continuous operation.

A nebulizer with compressor (E0570) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It is only AC powered.

A portable compressor (K0501) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It must have battery or DC power capability and may have an AC power option.

A light duty adjustable pressure compressor (K0269) is a pneumatic aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m, but is capable only of intermittent operation.

Code K0270 describes an ultrasonic generator used with a small volume chamber for medication delivery which is capable only of intermittent operation.

Code E0575 describes a large volume ultrasonic nebulizer system which is used for medication and humidification delivery, and which is capable of continuous operation.

*Accessories:*

Code A7003, A7005, and A7006 include the lid, jar, baffles, tubing, T-piece and mouthpiece. In addition, code A7006 includes a filter.

Code A7004 includes only the lid, jar and baffles.

Code A7012 describes a device to collect water condensation which is placed in line with the corrugated tubing used with a large volume nebulizer.

***Inhalation Drugs:***

Unit dose form of an inhalation drug or a combination of drugs is one in which the medication is dispensed to a patient (1) in a bottle/vial/ampule which contains the dose usually used for a single inhalation treatment, and (2) in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent.

Concentrated form of a drug used for inhalation is one in which the drug is dispensed to a patient in a concentration which requires that a separate diluent (usually saline) be added to the nebulizer when the drug is administered to a patient.

***Coverage and Payment Rules***

For any item to be covered by Medicare, it must 1) fit into a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, “reasonable and necessary” are defined by the following coverage and payment rules.

A small volume nebulizer (A7003, A7004, A7005) and related compressor (E0570, K0501) are covered when:

- a. It is medically necessary to administer beta-adrenergics, anticholinergics, corticosteroids, and cromolyn for the management of obstructive pulmonary disease (ICD-9-CM codes 491.0 - 505), or

- b. It is medically necessary to administer gentamicin, tobramycin, amikacin, or dornase alfa to a patient with cystic fibrosis (ICD-9-CM code 277.00) or
- c. It is medically necessary to administer pentamidine to patients with HIV (ICD-9-CM code 042), or
- d. It is medically necessary to administer mucolytics (other than dornase alpha) for persistent thick or tenacious pulmonary secretions (ICD-9-CM code 786.4).

Use of inhalation drugs, other than those listed above, will be denied as not medically necessary.

For criterion (a) to be met, the physician must have considered use of a metered dose inhaler (MDI) with and without a reservoir or spacer device and decided that, for medical reasons, it was not sufficient for the administration of needed inhalation drugs. The reason for requiring a small volume nebulizer and related compressor/generator instead of or in addition to an MDI must be documented in the patient's medical record and be available to the DMERC on request.

If none of the drugs used with a nebulizer are covered, the nebulizer and its accessories/supplies will be denied as not medically necessary.

A large volume nebulizer (A7017), related compressor (E0565 or K0269), and water or saline (K0182 or K0529) are covered when it is medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis (ICD-9-CM code 277.00), bronchiectasis (ICD-9-CM code 494 or 748.61), or a tracheostomy (ICD-9-CM code V44.0 or V55.0). Combination code E0585 will be covered for the same indications. An E0565 or K0269 compressor and filtered nebulizer (A7006) are also covered when it is medically necessary to administer pentamidine to patients with HIV (ICD-9-CM code 042). If a large volume nebulizer, related compressor/generator, and water or saline are used predominantly to provide room humidification it will be denied as noncovered.

Because there is no proven medical benefit to nebulizing particles to diameters smaller than achievable with a pneumatic model, when a small volume ultrasonic nebulizer (K0270) is ordered, it will be reimbursed at the least costly alternative of a pneumatic compressor (E0570).

Similarly, a large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor. However, since code E0575 is in a different payment category than pneumatic compressors, payment for a least costly alternate cannot be made. Therefore, when an E0575 nebulizer is provided, it will be denied as not medically necessary as will any related accessories and supplies.

A battery powered compressor (K0501) is rarely medically necessary. If this compressor is provided without accompanying documentation which justifies its

medical necessity, and the coverage criteria for code E0570 are met, payment will be based on the allowance for the least costly medically acceptable alternative, E0570.

Other uses of compressors/generators will be considered individually on a case by case basis, to determine their medical necessity.

*Accessories:*

A large volume pneumatic nebulizer (E0580) and water or saline (K0182 or K0529) are not separately payable and should not be separately billed when used for patients with rented home oxygen equipment.

Disposable large volume nebulizers (A7007 and A7008) are noncovered under the DME benefit because they are convenience items. A nondisposable unfilled nebulizer (A7017 or E0585) filled with water or saline (K0182, K0529) by the patient/caregiver is an acceptable alternative.

Kits and concentrates for use in cleaning respiratory equipment will be denied as noncovered.

Accessories are separately payable if the related aerosol compressor and the individual accessories are medically necessary. The following table lists the compressor/generator which is related to the accessories described. Other compressor/generator/accessory combinations are considered medically unnecessary.

<b>Compressor/ Generator</b>	<b>Related Accessories</b>
<u>Compressor/Generator</u>	<u>Related Accessories</u>
E0565	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015 A7017, E1372,
E0570	A4621, A7003, A7004, A7005, A7006, A7013, A7015
E0585	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015
K0269	A7006, A7014
K0270	A7014, A7016
K0501	A4621, A7003, A7004, A7005, A7006, A7013, A7015

This array of accessories represents all possible combinations but it may not be appropriate to bill any or all of them for one device

The following table lists the usual maximum frequency of replacement for accessories. Claims for more than the usual maximum replacement amount will be

denied as not medically necessary unless the claim is accompanied by documentation which justifies a larger quantity in the individual case.

<b>Accessory</b>	<b>Usual maximum replacement</b>
A4619	One/month
A4621	One/month
A7003	Two/month
A7004	Two/month (in addition to A7003)
A7005	One/6 months
A7006	One/month
A7010	One unit (100 ft.)/2 months
A7011	One/year
A7012	Two/month
A7013	Two/month
A7014	One/3 months
A7015	One/month
A7016	Two/year
A7017	One/3 years
E1372	One/3 years

*Inhalation Drugs and Solutions:*

For all inhalation drugs and solutions, claims for dispensed quantities greater than would be reasonable based on usual suggested dosing guidelines will be denied as not medically necessary unless accompanied by medical necessity documentation justifying these unexpected quantities. The pharmacist is responsible for assessing how much inhalation solution a patient is actually using. Considering this information, the pharmacist is responsible for assuring that the patient usually has no more than one month's supply on hand at any time.

The following table represents the maximum milligrams/month of inhalation drugs that would be reasonably billed for each nebulized drug. Claims for more than these amounts of drugs will be denied as not medically necessary unless accompanied by documentation which justifies a larger amount in the individual case.

Acetylcysteine:	up to 74 grams/month
Albuterol sulfate:	up to 465 mg/month
Atropine:	up to 186 mg/month
Bitolterol:	up to 434 mg/month
Cromolyn sodium:	up to 2480 mg/month (248 units/month)
Dornase alpha:	up to 78 mg/month
Glycopyrrolate :	up to 75 mg/month



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Ipratropium bromide:	up to 93 mg/month
Isoetharine :	up to 930 mg/month
Isoproterenol:	up to 450 mg/month
Metaproterenol:	up to 2800 mg/month (280 units/month)
Pentamidine :	up to 300 mg/month
Terbutaline :	up to 186 mg/month
Sterile saline or water, up to 5cc/unit (J7051):	up to 186 units/month
Saline solution, metered dose, 10 ml/unit (K0283):	up to 60 units/month
Distilled water, sterile water, or sterile saline in large volume nebulizer:	up to 18 liters/month

When a “concentrated form” of an inhalation drug is dispensed, separate saline solution (J7051 or K0283) used to dilute it will be separately reimbursed. Saline dispensed for the dilution of concentrated nebulizer drugs must be billed on the same claim as the drug(s) being diluted. If the unit dose form of the drug is dispensed, separate saline solution (J7051 or K0283) will be denied as not medically necessary. Water or saline in 1000 ml quantities (K0182 or K0529) are not appropriate for use by patients to dilute inhalation drugs and will therefore be denied as not medically necessary if used for this purpose. These codes are only medically necessary when used in a large volume nebulizer (A7017 or E0585).

Albuterol, bitolterol, epinephrine, isoetharine, isoproterenol, metaproterenol, and terbutaline are all bronchodilators with beta-adrenergic stimulatory effect. It would rarely be medically necessary for a patient to be using more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Ipratropium bromide, atropine, and glycopyrrolate are all anticholinergics. It would rarely be medically necessary for a patient to be using any more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Dornase alpha is covered for patients with cystic fibrosis (ICD-9-CM 277.00) who have a history of 2 respiratory infections requiring parenteral antibiotics during the year prior to initiation of dornase alpha and have a forced vital capacity equal to or greater than 40% of predicted value.

Because of the difference in preparation costs, the allowance per mg. for a single drug dispensed as a unit dose formulation (e.g., J7619KO) will be higher than the allowance per mg. for the same drug dispensed in a concentrated form (e.g., J7618). However, if multiple inhalation drugs are dispensed in a single container, only one of the drugs (i.e., that drug billed with the KP modifier) will be reimbursed at the higher allowance, whereas the other drug(s) (i.e., those billed with the KQ modifier) will be reimbursed at the same allowance as the concentrate. (See Coding Guidelines section for explanation of the KO, KP, and KQ modifiers.)

A monthly dispensing fee (E0590) for each covered drug or combination of drugs used in a nebulizer will be paid in addition to payment for the drug or drugs. This dispensing fee will be based on the drug dispensed, and not on the number of unit dose vials dispensed. Also, if two or more drugs are combined in single unit dose vials only one dispensing fee will be paid per drug combination per month. The dispensing fee(s) must be billed on the same claim as the dispensed inhalation drug(s). A dispensing fee is not separately billable or payable for saline, whether used as a diluent or for humidification therapy.

Charges for the drugs, diluent, and dispensing fees may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DMERC for nebulizer drugs.

Aerosol compressors and small volume ultrasonic generators will be grandfathered according to the provisions of the general DMERC Grandfathering policy, Sections A and B, if the approval did not conflict with national Medicare policy. In addition, if equipment with dates of service before the effective date of this policy was approved by the DMERC, it will also continue to be reimbursed. Appropriate accessories, supplies, and drugs will be covered if the equipment had been approved by the local carrier or the DMERC and the approval did not conflict with national policy. However, large volume ultrasonic generators (E0575) are not covered unless payment for the equipment was made by a local carrier prior to transition to the DMERC. For all items, even when coverage is grandfathered or continued, the frequency parameters listed in the policy will be applied. Also, coding for inhalation drugs and resulting reimbursement will be according to the DMERC policy.

### **Coding Guidelines**

The billing unit for most inhalation drugs is per milligram (mg.) of the drug dispensed. The billing unit of J7631, J7668, and J7669 is per 10 milligrams (10 mg.) of the drug dispensed. The billing unit of J7608 is per gram (gm.) of the drug dispensed. The billing unit of J2545 and J7682 is per 300 milligrams (300 mg.) of the drug dispensed.

When inhalation drugs are dispensed as a single drug formulation, the coding of a unit dose form or a concentrated form (see Definitions section) is determined by the formulation of the drug as it is dispensed to the patient. If a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol) which is then dispensed to the patient in single-dose bottles/vials/ampules, the inhalation solution is billed as the unit dose form, not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. When two or more drugs are combined by a pharmacist and

dispensed to the patient in the same unit dose container, all of the drugs are billed using the unit dose form code. However, the KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s). When two or more drugs are combined, the use of the KP and KQ modifiers should result in a combination that yields the lower cost to the beneficiary.

**Whenever a unit dose form code is billed, it must have either a KO, KP, or KQ modifier. If a unit dose code does not have one of these modifiers, it will be denied as an invalid code. The KO, KP, and KQ modifiers are not used with the concentrated form codes.**

The concentration of the drug in the dispensed solution can be converted to mg. or gm. as follows: A solution with a labeled concentration of 1% has ten (10) mg. of drug in each milliliter (ml.) of solution. Therefore, a 0.083% albuterol solution has 0.83 mg. of albuterol in each ml. of solution. Since albuterol 0.083% solution typically comes in a 3 ml. vial/ampule, each vial/ampule contains 2.5 mg. of albuterol ( $3 \times .83 = 2.5$ ). If a pharmacist provides 120 ampules of 0.083% albuterol solution each containing 3 ml., the billed units of service would be 300 ( $2.5 \times 120$ ) units (1 unit = 1 mg.) of code J7619KO. One unit of E0590 would be billed, which would represent the dispensing fee for the albuterol for the entire month.

When billing unit dose solutions which combine two or more drugs in a single container, each drug must be listed on a separate claim line. For example, if a pharmacist provides 120 ampules of a solution containing a combination of 2.5 mg. of albuterol and 20 mg. of cromolyn in each 3 ml. ampule, the pharmacist would bill J7619KQ 300 units for the albuterol ( $2.5 \text{ mg} \times 120 \text{ doses} = 300$ ) (1 unit = 1 mg.) and J7631KP (unit dose cromolyn) 240 units ( $20 \text{ mg/amp} \div 10 \text{ mg./unit} \times 120 = 240$ ) (1 unit = 10 mg.) for the cromolyn. One unit of E0590 would be billed which represents the dispensing fee for the combined solution for the entire month. There should be no separate billing for saline diluent.

Pharmacists should note that the correct concentration figure must be used to determine the number of mg. of drug dispensed. For example, if a pharmacist takes 0.5 ml. of a concentrated 0.5% albuterol solution and dilutes it with 2.5 ml. of saline to give a 3 ml. unit dose solution which is dispensed to the patient, each vial contains 2.5 mg. of albuterol ( $0.5 \text{ ml.} \times 5.0 \text{ mg/ml} = 2.5 \text{ mg.}$ ), not 15 mg. ( $3 \times 5.0$ ).

When a drug is provided in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent in a multidose container, use code J7699.

Code J7699 is also used for an inhalation drug administered by a nebulizer which does not have a valid specific J or K code. If two or more drugs are combined in the same unit dose container, bill specific J or K codes when possible and J7699 only for individual drugs which do not have a specific J or K code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate specific J or K codes will be denied for invalid coding.

Code E0585 is used when a heavy duty aerosol compressor (E0565), durable bottle type large volume nebulizer (A7017), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code A7017 is billed for a durable, bottle type nebulizer when it is used with a K0269 compressor or a separately billed E0565 compressor. Code A7017 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as A7017, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Code E1375 (Nebulizer, portable with small compressor, with limited flow) is not valid for claim submission to the DMERC. Use code E0570 or K0501 instead.

Code A4323 (Sterile saline irrigation solution, 1000 ml) is not valid for saline solutions used with nebulizers.

### ***Documentation***

An order for all equipment, accessories, drugs, and other supplies related to nebulizer therapy must be signed and dated by the ordering physician and kept on file by the supplier. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container, or (b) the name of the drug and the number of milligrams/ grams of drug in the dispensed solution and the volume of solution in that container. Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. Examples of (b) would be: albuterol 1.25 mg. in 3 ml. saline; or albuterol 2.5 mg. and cromolyn 20 mg. in 3 ml. saline. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml. qid and prn - max 6 doses /24 hr.; or one ampule q 4 hr prn; or 0.5 ml. diluted with saline to 3.0 ml. tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

A narrative diagnosis and/or an ICD-9 diagnosis code describing the condition must be present on each order. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

The patient's medical record must contain information which supports the medical necessity for all equipment, accessories, drugs, and other supplies that are ordered.

Except for the situations described below, this information does not have to be submitted with the claim but should be available to the DMERC on request.

Claims for K0501 must be accompanied by documentation of the need for the battery feature.

Claims to the DMERC for E0575 which were approved by a local carrier prior to transition to the DMERC must be submitted hardcopy, with a copy of the documentation demonstrating previous payment for the equipment by the local carrier.

When billing for quantities of nebulized inhalation drugs or nebulizer accessories and supplies greater than those described in the policy as the usual maximum amounts, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity for the higher utilization.

If more than one beta-adrenergic or more than one anticholinergic inhalation drug is billed during the same month, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity of concurrent use.

When code E1399 is billed for miscellaneous equipment or accessories, the claim must be accompanied by a clear description of the item including the manufacturer, the model name/number if applicable, and the medical necessity of the item for that patient. When code J7699 is billed for miscellaneous inhalation drugs, the claim must be accompanied by the detailed order information described above, a clear statement of the number of ampules/bottles of solution dispensed, and documentation of the medical necessity of the drug for that patient.

In all of the situations listed above, the documentation should be attached to each hard copy claim (as when physician narrative documentation is required) or entered in the HA0 record of each electronic claim.

Refer to the *Supplier Manual* for more information on orders, medical records, and supplier documentation.

### ***Effective Date***

For claims with dates of service on or after January 1, 2000.

This is a revision to a previously published policy.